

REMARKS

Claim Status

Prior to this amendment, claims 1-45 were pending, claims 1-3, 15-17, 34-36, and 43 were examined, and claims 4-14, 18-33, 37-42, and 44-45 were withdrawn.

With the entry of this amendment, claims 1-45 remain pending, claims 36 and 43 are amended, and claims 4-14, 18-33, 37-42, and 44-45 remain withdrawn.

Objections to the Specification

Description of Figure 1

The Office objects to the specification for failing to provide a description for Figure 1, as set forth in 37 C.F.R. § 1.74, which reads in its entirety as follows.

When there are drawings, there shall be a brief description of the several views of the drawings and the detailed description of the invention shall refer to the different views by specifying the numbers of the figures and to the different parts by use of reference letters or numerals (preferably the latter).

The Applicant notes for the record that the as-filed specification meets the requirements of 37 C.F.R. § 1.74. It includes, at paragraph 66, a brief description of Figure 1, which refers to Figure 1 by number and to the different parts of Figure 1 by the letters "A" and "B." In the interest of a compact prosecution, the Applicant amends the specification to present this information in a more conventional format by providing a separate heading to introduce Figure 1, placing this heading on page 4 of the as-filed application. No new matter is added as a result of this amendment because the description provided under the heading is identical to that provided in paragraph 66 of the as-filed application.

Trademark Demarcation

The Office objects to the use of improperly demarcated registered mark "AquaGrow®." The specification has been amended to indicate the appropriate symbol for this mark in paragraphs 48, 56, and 66. Accordingly, the Applicant requests that the Office withdraw the objection.

Objection to Claim 36

The Office objects to the spelling of "dinoflagelates" and "chitrids" in claim 36. The Applicant amends the spelling to "dinoflagellates" and "chytrids," and thus requests that the Office withdraw the objection.

Rejection of Claims 1-3, 15-17, and 43 Under 35 U.S.C. § 112, 1st Paragraph

The Office rejects claims 1-3, 15-17, and 43 as failing to enable the subject matter of the invention, under 35 U.S.C. § 112, paragraph 1. According to the Office, the specification does not provide support to the claims, which correlates with the claim limitation of at least 12.5 micrograms DHA per gram fresh weight of shrimp. It states that the specification shows a percentage increase in DHA in shrimp fed algae, but does not teach whether the increase is relative to, for example, fresh weight, dry weight, or fatty acid. It also asserts that the data appears statistically insignificant. Also, according to the Office, the specification fails to provide support for the claim limitation of a DHA to EPA ratio of at least 2.0. It asserts that the disclosed shrimp "failed to have a DHA/EPA content even remotely close to 2.0 as required by the claims" and states that those algae, which increase DHA levels, do so to a degree that depends on the DHA content of the algae. [Office Action at page 5].

The Office concludes that it is unpredictable whether any particular algae will increase DHA when fed to shrimp and that the degree of any resulting increase is unpredictable. Therefore, certain feeding conditions are required to meet the claim limitations and the application does not disclose those conditions. According to the Office, the specification does not enable the claims because it would require undue experimentation to make the claimed shrimp.

The Applicant respectfully traverses. The specification provides sufficient direction for one of skill in the art to make any and all of the claimed shrimp. Paragraph 45 teaches a method of making shrimp that "could effectively elevate the DHA levels of the shrimp to above 12.5 μg DHA/g fresh weight of shrimp." It also discloses that feeding an identified DHA source of particular microalgae can achieve this elevation. [Specification at page 12]. It further discloses aquaculturally raised shrimp comprising a DHA/EPA ratio greater than about 2.0. [Specification at page 12]. Paragraphs 36, 42, and 48 teach aquaculture conditions for raising such shrimp. [Specification at pages 8-9 and 10-11].

Example 10 is not required to enable claims to an aquaculturally raised shrimp comprising more than 12.5 μg /g fresh weight; it is provided for the purpose of demonstrating that conventional sources of DHA can be replaced by organic sources of DHA. Example 10 was not intended to demonstrate a high level of enrichment of the shrimp, as described elsewhere in the specification. Rather, its purpose is to demonstrate that an organic source of DHA, such as microalgae, can effectively substitute for nonorganic sources of DHA, such as some fishmeal.

The Office's assertion that it is unpredictable whether any particular algae will increase DHA to the claimed levels does not support a finding that the claims are not enabled. "As long as the specification discloses at least one method for making . . . the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. § 112 is satisfied." [M.P.E.P. § 2164.01(b)]. The specification discloses at least four microalgal DHA sources that produce the claimed invention, *Cryptocodinium*, *Schizochytrium*, *Ulkenia*, and *Parietochloris*. [Specification at page 12].

Unpredictability is only one consideration in the overall consideration of enablement; others include the amount of direction provided by the inventor, the quantity of experimentation necessary to make the claimed invention, and the existence of working examples. [M.P.E.P. § 2164.01(a)]. The inventors have provided a detailed road map for making the claimed shrimp using production methods known in the art, requiring little experimentation. For example, Example 1 describes shrimp production systems well known in the art, particular feeds, such as a standard grow out feed, and feeding methods, such as a defined Finishing Feed Process. Example 1 further describes a DHA source of the microalga *Cryptocodinium cohnii* (200 g per kg feed) or *Schizochytrium sp* (300 g per kg feed). Both of these algae products are available commercially from the sources cited in the specification. The shrimp produced in this manner can be harvested, processed, and prepared for human consumption using conventional processes. In view of the extensive direction provided by the inventor, the small quantity of experimentation necessary to make the claimed invention, and the

presence of multiple working examples, the Applicant asserts that the claims are fully enabled by the specification.

In summary, the specification enables claims 1-3, 15-17, and 43, which recite shrimp with more than 12.5 μg DHA/g fresh weight of shrimp or a DHA to EPA ratio of at least 2.0. It teaches that these shrimp can be produced by feeding them a defined microalgal DHA source using previously disclosed methods. It would be straightforward for anyone skilled in the art of raising shrimp to use the disclosed production methods, including the disclosed known aquaculture and feeding methods, to produce the claimed shrimp when the "source of DHA [is] added at a level that provides DHA content in the feed from 5% of the total fat in the feed to 50% of the total fat in the feed." [Specification at page 12]. The Applicant has, therefore, demonstrated that the as-filed application enables the claims and requests that the Office withdraw the rejection of claims 1-3, 15-17, and 43 under 35 U.S.C. § 112, ¶1, with respect to enablement.

Rejection of Claim 43 Under 35 U.S.C. § 112, 2nd Paragraph

The Office rejected claim 43 under 35 U.S.C. § 112, 2nd paragraph, as indefinite for reciting the term "high," which the Office characterizes as a relative term with no referent. Without acquiescing in the rejection, the Applicant amends claim 43 to recite a shrimp containing a DHA level in excess of 12.5 μg per gram fresh weight. Support for the amendment can be found at paragraph 29, which discloses that the shrimp feed of the invention "can comprise a high level of DHA" and that this "DHA level is greater than 12.5 μg per gram fresh weight." [Specification at page 7]. The Applicant has, therefore, satisfied the requirements of 35 U.S.C. § 112, 2nd paragraph, with respect to

indefiniteness of amended claim 43 and, accordingly, requests that the Office withdraw the rejection.

Rejection of Claims 1-3, 34-36, and 43 Under 35 U.S.C. § 102(b)

Thinh et al., *Aquaculture* 170:161-173, 1999

The Office rejected claims 1-3, 34-36, and 43 under 35 U.S.C. § 102(b), as anticipated by Thinh et al., *Aquaculture* 170:161-173, 1999 ("Thinh"). According to the Office, Thinh fed algae to shrimp, resulting in shrimp having increased DHA levels. The Office asserts that the shrimp disclosed by Thinh are structurally indistinguishable from the claimed shrimp, in the absence of any identified differences between the two. [Office Action at page 7].

The Applicant respectfully traverses. A reference anticipates a claimed invention only if it teaches every element of the claim. [M.P.E.P. § 2131]. Thinh fails to disclose "shrimp," as defined in paragraph 17 of the application. "A "shrimp" and the plural "shrimp" are defined as a crustacean or crustaceans generally referred to as shrimp, prawn, or langostina, such as, but not limited to, members from the following genera: *Penaeus*, *Litopenaeus*, *Pandalus*, *Macrobrachium*, *Crangon*, *Cherax*, and *Metapenaeus*." [Specification at page 5]. Thinh, in contrast, teaches a microscopic organism of the genus *Artemia*, commonly called a brine "shrimp," but which is not a true shrimp considered edible by humans. Shrimp for human consumption, as described in the present invention, are generally decapod crustaceans, which live in fresh water. The microscopic brine shrimp *Artemia* live in salt water and are sold as novelty gifts, most commonly under the marketing name Sea-Monkeys.

Thinh does not teach "shrimp," thus does not teach every element of claims 1-3, 34-36, and 43 and cannot anticipate the invention. Accordingly, the Applicant requests that the Office withdraw its rejection of claims 1-3, 34-36, and 43 under 35 U.S.C. § 102(b), in view of Thinh.

Barclay et al., *J. World Aquaculture Soc.* 27:314-322, 1996

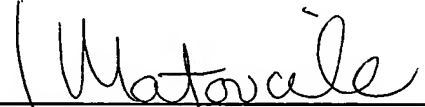
Finally, the Office rejected claims 1-3, 34-36, and 43 under 35 U.S.C. § 102(b), as anticipated by Barclay et al., *J. World Aquaculture Soc.* 27:314-322, 1996 ("Barclay"). The rationale for this rejection is identical to that applied to the rejection of these claims in view of Thinh. Barclay fed algae to *Artemia* (brine shrimp) and rotifers, which are not shrimp, but rather minute, usually microscopic, aquatic animals typically used as a source of live feed for aquatic larvae. The Applicant respectfully traverses for the same reasons cited above with respect to Thinh. A reference anticipates a claimed invention only if it discloses all the elements of the claim. Barclay does not teach "shrimp," thus does not teach every element of claims 1-3, 34-36, and 43 and cannot anticipate the invention. Accordingly, the Applicant requests that the Office withdraw its rejection of claims 1-3, 34-36, and 43 under 35 U.S.C. § 102(b), in view of Barclay.

For the foregoing reasons, the Applicant urges that claims 1-3, 15-17, 34-36, and 43 are in condition for allowance and respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims. Please grant any extensions of time required to enter this response, and charge our Deposit Account 06-0916 with any additional required fees.

Respectfully submitted,

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